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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/236,939	01/25/1999	PAUL J. GODOWSKI	P0854C1D4	9791

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EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/07/2002

LD

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/236,939

Applicant(s)

Godowski

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 4, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 31-44 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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- 1) Claims 31 to 44 are pending in the instant application.
- 2) The request filed on 04 February of 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/236,939 is acceptable and a CPA has been established. An action on the CPA follows.
- 3) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 5) Claims 31 to 44 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 5 of Paper Number 11. Applicant has traversed this rejection on the premise that the claimed isolated nucleic acid has utility in the diagnosis and treatment of breast and liver cancer. This alleged utility is based upon the disclosure in Table 3 on page 96 of the instant specification that HPTKA6 mRNA is expressed in a cell line that derived from a breast cancer and a cell line derived from a liver cancer whereas HPTKA6 mRNA is not expressed in breast and liver tissue. The table shows that, of all of the cell lines tested, HPTKA6 mRNA was expressed as the highest level in the cell line MCF-7. One of ordinary skill in the art, however, would not accept these results as supporting a conclusion that the expression of HPTKA6 mRNA in a liver of breast sample is diagnostic for cancer simply because cell lines are not necessarily representative of the cancers from which they were derived. To illustrate this fact, the Jones et al.

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publication (Cancer Genetics and Cytogenetics 117:153-158, 2000) is being cited because it shows that different MCF-7 cell stocks are known to not even be predictive of one-another. The first sentence in the "DISCUSSION" section of Jones et al. states that "MCF-7 cell line variants show a number of different features, including proliferation rates, ER and progesterone receptor levels, and estrogen and anti-estrogen responses and tumorigenicity", "as well as ER mRNA levels" "and expression of estrogen responsive genes BCE1 (coding for the pS2 protein) and *cathepsin D*." The cells employed by Applicant in Table 3 of instant application are cell lines, not cancer cells. Whereas these cell lines have been derived from tumor cells, it is well known in the art that cell lines are prone to change genetically as they are propagated. As indicated by the text in the first full paragraph on page 157 of Jones et al., cell lines like MCF-7 were known to undergo genetic alterations including the duplication and loss of specific regions of chromosomes as well as the duplication and loss of entire chromosomes (aneuploidy) during propagation. Whereas the gross morphology and physiology of cell lines such as MCF-7 and Hep-3 are accepted as being representative of the tissue types from which they were derived, as well as cancers of those specific tissues, one would not expect the expression of a particular gene in a cell line to be predictive of the expression of that gene in the primary cancer from which that cell line was derived or in the tissue type from which that cancer arose because one does not know if that expression is a consequence of a genetic alteration during oncogenesis or as a result of genetic alterations which have occurred during the *in vitro* propagation of that cell line.

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One of ordinary skill in this art would not believe that the expression of HPTKA6 mRNA in a breast or liver sample is diagnostic for cancer based upon the results presented in the instant specification because these results are based upon a single cell line from each tissue type and because no primary cancers were tested. If Applicant had consistently detected the expression of HPTKA6 mRNA in several different breast and liver cell lines or had demonstrated the expression of that mRNA in at least one primary breast or liver cancer, then an artisan might have a reasonable expectation that HPTKA6 mRNA was a marker for cancers in these tissues. However, an artisan would not accept the evidence that HPTKA6 mRNA is expressed in a single breast cell line and a single liver cell line, but not in breast or liver, as reasonably supporting a conclusion that HPTKA6 mRNA expression is diagnostic for a specific cancer.

6) Claims 31 to 44 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Claims 31 to 44 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Johnson et al. publication (P.N.A.S. 90:5677-5681, Jun. 1993) for those reasons of record. This publication expressly disclosed that the protein of the instant invention was associated with breast cancers and demonstrated this associated in Figure 2 and 3 by showing the increased expression of mRNA encoding that protein in a **plurality** of breast cancer cell lines. To antedate a reference, Applicant must show that they were in possession of as much of the invention as the

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reference. Applicant has not demonstrated a knowledge of an association between HPTKA6 mRNA expression and breast cancer before the publication date of Johnson et al.

8) Claims 31 to 33, 35 to 38 and 40 to 44 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Di Marco et al. publication (J. Biol. Chem. 268:24290-24295, 15 Nov. 1993) for those reasons of record. This reference disclosed that the protein described therein was a receptor for Nerve Growth Factor (NGF), a compound of clinical significance. Applicant has not demonstrated a knowledge of an association between HPTKA6 and NGF action before the publication date of Di Marco et al.

9) Claims 41 to 44 stand rejected under 35 U.S.C. 102(b) as being anticipated by the Klein et al. publication (EMBO J. 8(12):3701-3709, 1989) for those reasons of record. Applicant's arguments with respect to mouse and human sequences is nonsense. The instant claims are directed to "an isolated nucleic acid molecule". There is no limitation in the claims as to the origin of the isolated nucleic acid molecule. Applicant's argument that claim 41 is limited to "stringent conditions" has no basis in fact. Applicant is advised that the last form of claim 41 can be found in Paper Number 14, filed 27 June of 2001. No amendment to the claims has been subsequently presented. This rejection is maintained because Applicant has failed to identify a single limitation in these claims which is not met by the Klein et al. publication.

10) Applicant's arguments filed 04 February of 2002 have been fully considered but they are not persuasive for those reasons given above.

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11) All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800